



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al.

Examiner: S. HUI

Serial No.: 09/654,227

Group Art Unit: 1617

Filed: August 31, 2000

Title: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

**COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants have the following comments on the Statement of Reasons for Allowance which accompanied the Notice of Allowance and Issue Fee(s) Due mailed July 2, 2004. The Issue Fee(s) are being paid concurrently.

The Examiner (at page 3, lines 7-9) refers to the unobviousness of micronizing "synthetic progesterone." Applicants' declarations, however, address only the unobviousness of micronizing the specific synthetic progesterone, drospirenone, which is the agent recited in the claims.

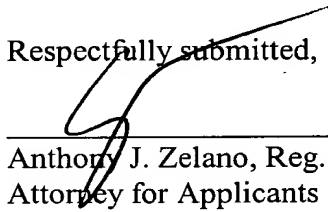
At page 3, lines 11-13, it is stated: "The micronized drospirenone will be degraded even more rapidly because the micronization of drospirenone expose [sic] the drug particles in the stomach (acidic)." (Emphasis added.) Based on "the declaration and applicant's remarks .. found persuasive" by the Examiner, it is clear that the Examiner is referring to what one of ordinary skill in the art would have expected if micronization was presumed to increase solubility. Thus, it would be more accurate to state: If it were presumed that micronization would be expected to increase solubility of drospirenone, then micronized drospirenone would have been expected by one of ordinary skill in the art to be degraded even more rapidly because the micronization of

drospirenone exposes the drug particles in the stomach (acidic).

At page 3, lines 13-16, the Examiner refers to "data presented in the declaration filed December 9, 2003." The only declaration "data" presented by applicants relating to nonobviousness was in the Declaration of Dr. Lipp filed with the Reply of March 10, 2003. (Apparently, a copy of the Lipp Declaration was provided with the Reply filed December 4, 2003, which may have led to the impression it was first filed in December.) The Lipp Declaration includes data in Appendix A merely confirming that "drospirenone is instable in acidic environment," as otherwise established by the prior art of record and as stated in the Examiner's Reasons for Allowance.

Regarding the Examiner's Amendment, applicants would like to point out that the amendments were made at applicants' request for cautionary purposes in view of the recent decision of the Court of Appeals for the Federal Circuit in *Smithkline-Beecham Corp. v. Apotex Corp.*, \_\_\_ F.3d \_\_\_, 70 USPQ2d 1737 (Fed. Cir. 2004).

Respectfully submitted,

  
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Attorney Docket No.: PLOVIN-0001-A

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